

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE**

PLAINTIFF'S STATEMENT OF ADDITIONAL MATERIAL FACTS

I. Consciousness

1. Consciousness “is not an off-or-on switch,” but instead “exists in a continuum of varying degrees.” (Def. Ex. 15, Van Norman Rep. at 14; *see also* Def. Ex. 13, Antognini Dep. 76:12-22 (consciousness is not “an all or none phenomenon,” but “is really a spectrum”)).

RESPONSE:

2. “Consciousness” and “responsiveness” are separate and distinct concepts; a person can be conscious and sensate—that is, able to perceive sensory experiences, including pain—yet unable to respond and demonstrate that consciousness. (Def. Ex. 15, Van Norman Rep. at 11.)

RESPONSE:

3. A lack of responsiveness or movement in no way indicates that a person is “unconscious” such that they cannot experience sensations of pain and suffering. (Def. Ex. 15, Van Norman Rep. at 11.)

RESPONSE:

4. “A lack of consciousness does not necessarily mean that an individual cannot feel pain.” (Def. Ex. 11, Stevens Rep. at 8.)

RESPONSE:

5. Rather than using the term “consciousness,” which has no precise medical definition, the “proper terminology refers to depth of responsiveness, levels of sedation/analgesia, and general anesthesia.” (Def. Ex. 11, Stevens Rep. at 9-11 (citing American Society of Anesthesiologists, Committee on Quality Management and Departmental Administration, *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*, October 23, 2019, available at <https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia> (last visited March 24, 2022)).)

RESPONSE:

6. A state of “general anesthesia” is defined as a combination of analgesia or antinociception (lack of pain), amnesia (lack of recall), lack of awareness, and immobility with significantly painful or noxious surgical stimulation. (Def. Ex. 15, Van Norman Rep. at 6 (citing Brown, EN, Purdon PL, Akeju O, Solt K, Monitoring the state of the brain and central nervous system during general anesthesia and sedation. Miller’s Anesthesia p. 1279, Gropper MA, Miller RD, Eds, Elsevier Inc., Philadelphia, PA, 2021)).

RESPONSE:

7. Because noxious or surgical stimulation can vary in type and degree, any discussion of whether a particular drug can “produce unconsciousness” is nonsensical unless it

defines the particular stimulus against which the drug must produce and maintain unresponsiveness. (Def. Ex. 15, Van Norman Rep. at 14.)

RESPONSE:

8. In general, the more severe a stimulus is, the deeper the “unconscious” state must be to maintain unresponsiveness throughout the duration of the stimulus, and thus the deeper the anesthesia generally must be. (Def. Ex. 15, Van Norman Rep. at 14; Def. Ex. 13, Antognini Dep. 77:21-23 (“[Y]ou look at how much anesthetic is required to blunt or oblate those types of responses.”).)

RESPONSE:

9. Less anesthetic may be required for the stimulus of a trapezius squeeze than for stimulus by surgical incision. (Def. Ex. 13, Antognini Dep. 77:23-78:4.)

RESPONSE:

10. Unresponsiveness without unconsciousness can occur due to 1) physical impediments, e.g., a person may be given a drug that paralyzes their muscles so that the surgeon can work within the belly, and yet still be fully awake; 2) nonphysical impediments, such as fear or surprise, e.g., being “frozen” by terror; and 3) physiological problems within the brain itself, e.g., strokes and drug effects that interrupt outgoing nerve signals and prevent purposeful movement even though muscles are not paralyzed and the person is conscious of their surroundings and can feel pain (something called “locked-in syndrome”). (Def. Ex. 15, Van Norman Rep. at 11.)

RESPONSE:

11. When asked how he can be sure he is correctly determining a prisoner's consciousness, the Warden responded, “[n]othing is sure, you just know and go with it.” (Def. Ex. 20, Mays Dep. at 115:21-116:1.)

RESPONSE:

12. The Warden stated that he would “not necessarily” want to know whether a prisoner could feel pain from the administration of the second two drugs—even though that is supposedly the purpose of performing the consciousness check—and more generally that he is not concerned with how much pain a prisoner feels during an execution. (Def. Ex. 20, Mays Dep. at 311:24-312:16.)

RESPONSE:

II. Midazolam

13. Midazolam is a benzodiazepine drug, like diazepam (Valium) and alprazolam (Xanax). (Def. Ex. 11, Stevens Rep. at 12; Def. Ex. 9, Antognini Rep. at 8.)

RESPONSE:

14. Midazolam is classified as a sedative hypnotic, meaning it can cause sedation and hypnosis. (Def. Ex. 11, Stevens Rep. at 18; Def. Ex. 15, Van Norman Rep. at 6; Def. Ex. 13, Antognini Dep. 212:1-2.)

RESPONSE:

15. Midazolam is not classified as an anesthetic. (Def. Ex. 11, Stevens Rep. at 27; Def. Ex. 15, Van Norman Rep. at 6; Def. Ex. 13, Antognini Dep. 212:11-12.)

RESPONSE:

16. In at least one study, “the ceiling dose was approached (although not reached) during a study of midazolam with administration of as little as 0.4 mg/kg of midazolam, (i.e. 40 mg in a 100 kg person), a dose well below that proposed in the Tennessee protocol.” (Def. Ex. 15, Van Norman Rep. at 22 (citing Gamble JAS, Kawar P, Dundee JW, Moore J, Briggs LP. Evaluation of midazolam as an intravenous induction agent. *Anaesthesia* 1981; 36:868-73).)

RESPONSE:

17. The ceiling effect of midazolam means that it cannot achieve general anesthesia no matter what dose is administered. (Def. Ex. 15, Van Norman Rep. at 22 (“[A]lthough the dose of midazolam proposed in the Tennessee protocol is high, it exceeds that of midazolam’s maximum clinical effect, and does not increase the likelihood of unconsciousness compared to doses that have previously been shown to not provide unconsciousness during severely painful or other severely noxious stimuli.”); Def. Ex. 11, Stevens Rep. at 23 (“[M]idazolam has a ceiling effect, which occurs before anesthesia is obtained.”).)

RESPONSE:

III. Training

18. The Warden and Execution Team referred to the practice sessions as “band practice” up until their legal department advised against it. (Def. Ex. 20, Mays Dep. at 287:25-288:12.)

RESPONSE:

19. The logs documenting the Execution Team’s practice sessions list fictitious prisoner names including “Wild Bill,” “Con Demned,” “Annie Oakley,” “Doc Holliday,” “Tom Thumb,” “John Henry,” and “Billy the Kid.” (Def. Ex. 20, Mays Dep. at 285:8-287:12.)

RESPONSE:

20. The Warden stated that use of the names listed above “most definitely” indicates the Execution Team was taking the practices seriously. (Def. Ex. 20, Mays Dep. at 285:8-20.)

RESPONSE:

IV. Preparation and Handling of Lethal Injection Chemicals

21. The training required for handling lethal injections chemicals (“LIC”) includes the following:

[A] really long list, but it includes things like how you reconstitute medications; how do you know if you have a correct volume; how do you equilibrate pressure within the vial and . . . the solution when you are . . . pulling up a certain amount or reconstituting. . . . How do you assure that the medication will not be contaminated? How do you handle the syringe and needle, you know? How do you hold it? I mean, they seem like simple things, but they are not. You know, what our natural instincts naturally tell you about how we handle things is very different when we handle sterile preparations. You know, the way you even attach the needle to the hub, there is a technique for that. The way you inject. What can you hold when you are pushing the needle into an IV bag. What can you touch when you are handling the vial? . . . [L]ike I said, it sounds simple to a lay person because it seems like a no-brainer, but it is not.

Def. Ex. 29, Almgren Dep. at 153:10-154:7.

RESPONSE:

22. The Drug Procurer “lacks the training and professional qualifications necessary to understand how to properly store and handles LICs,” and “lacks attention to detail.” (Pl. Ex. 5, Almgren Rep. at 5.)

RESPONSE:

23. The Drug Procurer does not always make accurate entries to the drug inventory log. (Pl. Ex. 5, Almgren Rep. at 5 (citing Ex. 3, Drug Procurer Dep. at 299-301).)

RESPONSE:

24. The Executioner “does not follow USP Chapter 797 guidance on BUD assignment for all three of the LICs,” “does not have any special or advanced aseptic technique

training,” and “has not been adequately trained to properly prepare the LICs.” (Pl. Ex. 5, Almgren Rep. at 5.)

RESPONSE:

V. Compounding and Drug Quality

25. USP monographs for a particular API set forth quality requirements and the tests that must be used to verify that each quality requirement is met. (Pl. Ex. 5, Almgren Rep. at 2.)

RESPONSE:

26. USP quality standards must be followed for the drug to be labelled USP grade. (Pl. Ex. 5, Almgren Rep. at 2, Pl. Ex. 3, Patel Dep. at 36:18-25.)

RESPONSE:

27. Other possible chemical grades include EP grade, meaning the medication complies with the European Pharmacopeia quality requirements, and BP grade, meaning the medication complies the British Pharmacopeia grade. (Pl. Ex. 5, Almgren Rep. at 2.)

RESPONSE:

28. The two batches of midazolam API that the Pharmacy purchased to fill TDOC’s orders were not tested pursuant to the USP, but instead were subjected only to EP and BP standards. (Pl. Ex. 22, Defts. Supp. Resp. 11.18.2021 000003, 000005.)

RESPONSE:

29. Because the quality standards set by the USP for midazolam are different than those set by the EP and BP, the two batches of API cannot be used to compound USP grade midazolam without further analysis using USP quality standards and methodologies. (Pl. Ex. 5, Almgren Rep. at 2-4.)

RESPONSE:

30. USP also sets standards for testing compounded preparations to ensure that standards for potency, impurities, particulates, endotoxins, pH, and sterility are met. If a compounded preparation is not subject to all the required tests or fails any of the required tests, it should not be used because the quality may be subpar and its pharmacological activity is unpredictable. (Pl. Ex. 5, Almgren Rep. at 11-12.)

RESPONSE:

31. Nearly every preparation the Pharmacy compounded for TDOC failed at least one test and/or was not subjected to all the tests required by the USP. (Pl. Ex. 5, Almgren Rep. at 11-14.)

RESPONSE:

32. Out of all the batches of potassium chloride and midazolam that the Pharmacy has compounded for TDOC, only a single batch of midazolam was tested for endotoxins. (Pl. Ex. 3, Patel Dep. 30:20-21, 58:12-17, 59:12-20.)

RESPONSE:

33. Two of the three of the potassium chloride preparations compounded by the Pharmacy and subjected to potency testing failed. (Pl. Ex. 8, Potassium Chloride Potency Results.)

RESPONSE:

34. A batch of midazolam also failed the USP required potency test. (Pl. Ex. 9, Midazolam Potency Result.)

RESPONSE:

VI. Pentobarbital

35. TDOC has long been aware that pentobarbital is available in Europe. (Ex. 12, PowerPoint Presentation).

RESPONSE:

36. On May 3, 2019, the date on which the Office of Legal Counsel for the United States Department of Justice issued an opinion (“OLC Memorandum”) that the Food and Drug Administration (FDA) does not have jurisdiction over drugs intended for use in lawful executions. (Pl. Ex. 26, OLC Memorandum, May 3, 2019.)

RESPONSE:

37. Even prior to the issuance of the OLC Memorandum, TDOC’s General Counsel, Debbie Inglis, never sought an exception to be allowed to import pentobarbital, and she knows of no attempts to obtain pentobarbital from overseas since 2017. (Def. Ex. 2, Inglis Dep. at 120:12-123:254.)

RESPONSE:

38. At the time of her deposition in this case, Ms. Inglis was not aware that the DEA has not intervened in any importation of execution drugs since the OLC Memorandum was issued. (Def. Ex. 2, Inglis Dep. at 162:21-24.)

RESPONSE:

39. TDOC wishes to obtain pentobarbital from overseas, so long as importation complies with federal regulations. (Def. Ex. 3, Drug Procurer Dep. at 230:7-22.)

RESPONSE:

40. Neither Ms. Inglis nor anyone else at TDOC has ever contacted the DEA or FDA about the OLC Memorandum. (Def. Ex. 2, Inglis Dep. at 162:25-163:7.)

RESPONSE:

41. The Federal Bureau of Prisons acquires the active pharmaceutical ingredient (API) for pentobarbital sodium from a domestic bulk manufacturer for use in executions. (Pl. Ex. 13, Bureau of Prisons Memorandum, Mar. 10, 2020).

RESPONSE:

42. The Arizona Attorney General's Office has located a supplier willing to supply the state with pentobarbital for use in executions. (Pl. Ex. 14, Letter Mark Brnovich, Arizona Attorney General to Arizona Governor Doug Ducey, Aug. 20, 2020).

RESPONSE:

43. The Arizona Department of Corrections has held a Drug Enforcement Administration license to import pentobarbital since at least 2014. (Pl. Ex. 15, Department of Justice, Importer of Controlled Substances Application: Arizona Department of Corrections, Docket No. DEA-392 (2018) *available at* https://www.deadiversion.usdoj.gov/fed_regs/imprt/app/2018/fr1214_2.htm; Pl. Ex. 16, Department of Justice, Importer of Controlled Substances Application: Arizona Department of Corrections, Docket No. DEA-861 (2021) *available at* https://www.deadiversion.usdoj.gov/fed_regs/imprt/app/2021/fr0723.htm; Pl. Ex. 17, Miranda Rivers, "DEA renews Arizona's permit to import execution drug," Tucson Sentinel (Sep. 5, 2014), available at https://www.tucsonsentinel.com/local/report/090514_execution_drug/dea-renews-arizonas-permit-import-execution-drug/).¹

¹ The Court may take judicial notice of matters of public record referenced in our Statement of Additional Material Facts, including press releases and information on government websites. *See Cary v. Cordish Co.*, 731 F. App'x 401, 407 (6th Cir. 2018) ("the court can take judicial notice of 'a fact that is not subject to reasonable dispute,' either because the fact 'is generally known within the trial court's territorial jurisdiction,' or it 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.'") (citing Fed. R. Civ. P. 201); *Beaver Cty. Ret. Bd. v. LA-Vision Inc.*, No. 1:07-CV-750, 2009 WL 806714, at *7 (S.D. Ohio Mar. 25, 2009) ("Press releases also are self-authenticating under evidentiary rule 902(6)"); *Rote v. Zel Custom Mfg., LLC*,

RESPONSE:

VII. Firing Squad

44. Defendants examined Mr. Turley at length on several topics directly related to the feasibility and implementation of execution by firing squad, including, but not limited to, Utah's firing squad protocol, the equipment used to carry out an execution by firing squad, the planning and construction of facilities used to carry out execution by firing squad, the maintenance and outfitting of the facilities and ballistics safety equipment used to carry out execution by firing squad, the selection and training of personnel to perform execution by firing squad, and the cost and resources associated with implementing a firing squad execution protocol. *See* Pl. Ex. 25, Turley 30(b)(6) Subpoena.

RESPONSE:

45. In support of the assertion that “[a] person may remain conscious or even mobile after receiving a fatal gunshot wound,” Defendants’ expert, Dr. Li, cites the following two examples: (1) a man who was shot in the left part of the chest with a shotgun with birdshot pellets smaller (.095 inch) than BBs (.18 inch), and (2) an individual who was shot once in the left back with a .25 ACP pistol. (Def. Ex. 17, Li Dep. at 244:17-245:4; 248:1-6.)

RESPONSE:

46. A .25 ACP pistol is a small caliber gun, which will produce less severe damage as compared to a large caliber, high velocity gun if the person is shot somewhere besides the head. (Def. Ex. 17, Li Dep. 249:19-21; 251:2-7.)

383 F. Supp. 3d 779, 785 (S.D. Ohio 2019) (“Official publications available electronically from a government website should be accepted by the court as self-authenticating”).

RESPONSE:

47. Utah, South Carolina, and the U.S. Military protocols all require the use of center-fired rifles, which are high velocity weapons, in their executions by firing squad. (Ex. 43, UDC 30(b)(6) Dep. 29:14-17; Pl. Ex. 11, South Carolina DOC Press Release; Def. Ex. 48, Williams Rep. at 9-12; see also Def. Ex. 8, Williams Dep. 62:6-8.)

48. South Carolina authorizes execution by firing squad. S.C. Code § 24-3-530.

RESPONSE:

49. An overview of South Carolina’s firing squad protocol is publicly available. (Pl. Ex. 11, South Carolina DOC Press Release).

RESPONSE:

50. The South Carolina DOC’s Capital Punishment Facility at Broad River Correctional Institution was renovated to include the capacity to perform an execution by firing squad. (Pl. Ex. 11, South Carolina DOC Press Release).

RESPONSE:

51. The South Carolina DOC added to the execution chamber: “a chair in which inmates will sit if they choose execution by firing squad. The chair is in a corner of the room away from the current electric chair, which cannot be moved. Bullet-resistant glass has been installed between the witness room and death chamber.” (Pl. Ex. 11, South Carolina DOC Press Release).

RESPONSE:

52. In South Carolina’s execution chamber, the “firing squad chair is metal with restraints and is surrounded by protective equipment. The chair faces a wall with a rectangular opening 15 feet away.” (Pl. Ex. 11, South Carolina DOC Press Release).

RESPONSE:

53. The South Carolina DOC spent about \$53,600 on supplies and materials to make these changes. (Pl. Ex. 11, South Carolina DOC Press Release).

RESPONSE:

54. South Carolina requires the use of rifles in its executions by firing squad. (Pl. Ex. 11, South Carolina DOC Press Release).

RESPONSE:

VIII. TDOC Execution Chamber

55. TDOC's current execution chamber measures around 16 by 19 feet. (Pl. Ex. 18, Gardiner Affidavit).

RESPONSE:

IX. TDOC Execution Related Costs

56. TDOC currently has budgeted \$400,000 for "Execution Related Services" for the 2022 fiscal year, which includes a \$62,000 pharmacological services cost per execution. (Pl. Ex. 19, TDOC Delegated Authority for Execution Related Services).

RESPONSE:

X. Physician Participation

57. The same physician who pronounces death in TDOC executions by lethal injection also pronounces death in executions by electrocution. (Pl. Ex. 20, Physician Dep. 26:22-25, 59:11-16).

RESPONSE:

58. Dr. Van Norman, along with the American Society of Anesthesiologists, the American Medical Association, and the American Board of Anesthesia, believes that "physicians

shouldn't participate in lethal injection." (Def. Ex. 10, Van Norman Dep. at 68:20-23; *see also id.* at 69:14-17 ("Prisoners are not patients, and executions are not medical procedures. And so, using medical skills to participate in nonmedical procedures is unethical.").)

RESPONSE:

Dated: April 13, 2022

Respectfully submitted,

/s/ David R. Esquivel

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CERTIFICATE OF SERVICE

I certify that on April 13, 2022, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent through the Court's electronic filing system to all parties indicated on the electronic filing receipt with includes:

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